PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP 03/06212	International filing date *(day/month/year)* 13.06.2003	Priority date *(day/month/year)* 01.07.2002
International Patent Classification (IPC) or both national classification and IPC A23L1/305		
Applicant UNILEVER N.V.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
20.12.2003	17.08.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Koch, J Telephone No. +31 70 340-4307

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/06212

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-30 as originally filed

Claims, Numbers

1-18 filed with telefax on 18.06.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1,3-16,18
	No:	Claims	2,17
Inventive step (IS)	Yes:	Claims	1,16
	No:	Claims	2-15, 17, 18
Industrial applicability (IA)	Yes:	Claims	1-18
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 2 and 17 is not new in the sense of Article 33(2) PCT.

2. Document D3 discloses (cf. § 62; example 2; claims 1, 2, 15, 16, 26, 27) methods that improve muscle mass maintenance and recovery.
For achieving this aim, a nutritional supplement comprising e.g. about 3,4 % hydrolyzed whey protein is administered to patients in need thereof (e.g. to elderly and sick).
The incorporation of hydrolyzed whey protein in the supplement results in a shorter period, in which the patient feels satiated and therefore leads to a rapid return of appetite (cf. § 62). Due to this appetite stimulating effect, it is suggested to use the nutritional supplement to avoid conditions of anorexia and/or protein-energy malnutrition.
To sum up, D3 teaches the use of nutritional supplements comprising hydrolyzed whey proteins, which function as satiety inhibitors, for the purpose of avoiding anorexia and/or protein-energy malnutrition, and thus for controlling calorie intake and body weight.
The subject-matter of claims 2 & 17 is therefore not novel (Article 33(2) PCT).

3. The documents D5 (cf. example 2) and D6 (cf. example 7) both disclose infant formulas comprising between 0,1 and 80 wt.% hydrolyzed whey protein.
With infant formulas being (at least potentially) the sole source of nutrients administered to the infant, the formulas implicitly contain an appropriate amount of calories to provide sufficient energy to the infant.
Whereas it is not explicitly stated in D5 or D6 that the administration of infant formulas to infants serves for controlling calorie intake and/or body weight, this is the obvious purpose of the respective compositions from the point of view of the person skilled in the art.
Claims 2 and 17 therefore appear to lack an inventive step (Article 33(3) PCT).

4. Dependent claims 3-15 & 18 do not contain any features which, in combination with the features of claims 1 or 17 respectively, to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:
In these claims, slight changes in the use / method of claim 2 and 17, respectively, are defined which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen.
Consequently, the subject-matter of claims 3-15 & 18 lacks an inventive step.

5. The document D1 is regarded as being the closest prior art to the subject-matter of claims 1 and 16 and shows nutritional compositions comprising e.g. whey protein, which are used for enhancing satiety (cf. e.g. claim 1).

5.1. The subject-matter of claim 1 and 16 differs from the disclosure of D1 in that whey proteins are administered in hydrolyzed form for enhancing satiety.

5.2. The subject-matter of claims 1 and 16 is therefore new (Article 33(2) PCT).

5.3. The problem to be solved by the present invention may therefore be regarded as the provision of an alternative compound, which enhances the feeling of satiety.

5.4. The solution to this problem proposed in claims 1 and 16 of the present application is considered as involving an inventive step (Article 33(3) PCT), because the prior art does not teach or suggest the use of hydrolyzed whey protein for enhancing satiety.

Claims

1. The use of a whey protein and/or whey protein hydrolysate in an edible composition, the whey protein and/or whey protein hydrolysate being able to induce the cellular release of glucagon-like-peptides and cholecystokinins, wherein the whey protein and/or whey protein hydrolysate on or after consumption of the edible composition induces an enhanced feeling of satiety.

2. The use of a whey protein and/or whey protein hydrolysate in an edible composition, the whey protein and/or whey protein hydrolysate being able to induce the cellular release of glucagon-like-peptides and cholecystokinins and wherein the composition is used to improve or control perception of body image, and/or to control body weight, and/or to control calorie intake and/or help adherence to a dietary plan.

3. The use according to either one of claims 1 or 2, wherein the whey protein hydrolysate comprises hydrolysates of β-lactoglobulin, α-lactalbumin or a mixture thereof.

4. The use according to claim 3, wherein the hydrolysates of β-lactoglobulin and α-lactalbumin are present in a weight ratio of from 5:1 to 1:5.

5. The use according to any one of the preceding claims, wherein the whey protein hydrolysate has a degree of hydrolysis in the range of from 1 to 20%.

6. The use according to any one of the preceding claims, wherein the whey protein and/or whey protein hydrolysate is

used in a total amount of from 0.1% to 80% by weight based on the weight of the composition.

7. The use according to any one of the preceding claims, wherein the edible composition is a food composition used in a weight loss or weight control plan.

8. The use according to any one of the preceding claims, wherein the edible composition meal replacement product.

9. The use according to claim 8, wherein the meal replacement product is a ready-to-drink liquid, a liquid produced from a soluble powdered product, a soup, a dessert, a bar, a cereal based or pasta based or noodle based product, or, a soluble powdered product.

10. A method for inducing satiety in a human or animal, the method comprising the step of administering to a human or animal by means of an edible composition, an effective amount of a whey protein and/or whey protein hydrolysate which is capable of inducing the cellular release of glucagon-like peptides and cholecystokinins.

11. A method for improving or controlling perception of body image, and/or controlling body weight, and/or controlling calorie intake and/or helping adherence to a dietary plan, the method comprising the step of administering to a human or animal by means of an edible composition, an effective amount of a whey protein and/or whey protein hydrolysate which is capable of inducing the cellular release of glucagon-like peptides and cholecystokinins.

12. The method according to either one of claims 10 or 11, wherein the edible composition comprises a total amount of from 0.1% to 80% by weight based on the weight of the composition of the whey protein and/or whey protein hydrolysate.

13. A liquid or flowable edible composition comprising protein, wherein the protein comprises 0.1 to 50% by weight based on the weight of the composition of a whey protein hydrolysate capable of inducing the cellular release glucagon-like-peptides and cholecystokinins, and wherein 50% or less of the total calories in the edible composition are provided by the protein

14. A liquid or flowable edible composition 0.1 to 80% by weight based on the weight of the composition of a whey protein hydrolysate capable of inducing the cellular release glucagon-like-peptides and cholecystokinins, and wherein the composition further comprises added vitamins and/or minerals selected from at least one of vitamins A, B1, B2, B3, B5, B6, B11, B12, biotin, C, D, E, H, and K and calcium, magnesium, potassium, zinc and iron.

15. The edible composition according to either one of claims 13 or 14, wherein the whey protein hydrolysate comprises hydrolysates of β-lactoglobulin, α-lactalbumin or a mixture thereof.

16. An edible composition in the form of a bar and comprising hydrolysates of β-lactoglobulin, α-lactalbumin or a mixture thereof in a total amount of from 0.1 to 80% by weight based on the weight of the composition.

17. The edible composition according to any one of claims 13 to 16, wherein the composition is used in a weight loss or weight control plan.

18. The edible composition according to claim 17, wherein the composition is a meal replacement product.